

ANNEX II.

PATENTABILITY INDEX

There are many elements the protection of which, in legal terms, is desirable (see the orange box below). However, not all of them are susceptible to patent, but a small group (in white) that, also, must have some characteristics, namely: **Novelty**, **Inventive Step** and **Industrial Application**.

An idea – Scientific Theories – Mathematical Methods – Art Creations – Commercial or Economical Activities – Computer Programs or Software – Objects (Products...)* – Presenting Information Methods – Vegetable or Animal Varieties – Images – Designs – Words or Sentences – Signs – Plays (Artistic, Literary, Scientific) – Procedures or Manufacturing Methods

*If it only provides an improvement to an existing product: Utility Model

Table 1. Different human creations are shown. In white, one can see human-made things/discoveries that could be patented. In orange, the ones that in case of being protected would need other kind of legal protection (non-patentable).

Traditionally, experts decide whether something is patentable or not. In an effort to assist those experts, we, the Valencia Biocampus iGEM team, are developing an intuitive formula that might be helpful for them to take a decision. The formula we propose is based in internationally accepted standards and articles related to the topic (see bibliography and references).

A. THE FORMULA

Extended equation

$$\text{Patentability Index [P.I.]} = \text{Morality (M)} \times \text{Novelty [N]} \times (\text{Inventive Step [A]})^{\log\left(\frac{\text{Inventive Step [A]} + \text{Industrial application [I]}}{2}\right)}$$

Please note that we introduce in the formula a non-legal term, morality.

Abbreviated equation

$$\text{P.I.} = \text{M} \times \text{N} \times (\text{A})^{\log\left(\frac{\text{A} + \text{I}}{2}\right)}$$

The numerical limits of the formula and the mathematical interpretation (modelling) of the P.I. value are shown at the end of Annex II.

How does the formula work?

By answering specific question the values of the different parameters in the equation can be introduced.

Previous questions (If any of the answers is “Yes” the invention could not be patented):

✚ Is your invention about or related to the following fields...			
- scientific theories			
and mathematical methods?	Yes	No	
- artistic/literary creations?	Yes	No	
- aesthetic creations?	Yes	No	
- schemes, rules and methods for			
performing mental acts,			
playing games or doing business,			
and programs for computers?	Yes	No	
- methods for presenting			
information?.	Yes	No	

Breakdown of terms

- **Morality (M). Values: 0/1**

The value of **M** is not arbitrary, but a result of a questionnaire. If any of the answers is “Yes” the term of morality automatically becomes zero.

✚ This invention relates to...			
- isolated genes?*	Yes	No	
- sequenced DNA?*	Yes	No	
- medical procedures?	Yes	No	
- embryonic stem cells?	Yes	No	
- methods of chromosome transfer?	Yes	No	
- mixing of human and animal species?	Yes	No	
✚ Could this invention result in...			
- denigration or human dignity?**	Yes	No	
- destruction of human life?	Yes	No	
- ownership of human life?	Yes	No	
- spread of pollution or disease?		Yes	No

- loss of genetic diversity?

Yes No

If the aim is to protect the DNA per se, it must be noted that patent eligible subject matter is “anything under the sun made by humans”. The relevant point here is not if the creation is a living or an inanimate thing, but if they are **products of nature, whether living or nor, or **human made inventions**.*

To sum up: DNA per se. Not patentable. ❌

Applications arose from the presence/use of that sequence. Patentable. ✅

***Given the very diversity of the use of dignity throughout the judicial world, human dignity could be understood as a set of three minimum elements: an ontological, a relational and a limited-state claims. The ontological one refers to “the inherent dignity of man”; the relational claim relates to the intrinsic worth and the recognition respect of it by others; finally the third claim recognize the intrinsic worth of individual requires that the state should be seen to exist for the sake of the individual human being, and not viceversa.*

- **Novelty (N). Values: 0/1.**

Similarly, **N** is calculated from the answers to several questions. If any of the answers is “Yes” the term of novelty automatically becomes zero.

✚ Is there a process or product identical to yours (prior state of art)?*	Yes	No
✚ Has the invention been used in public so its operation made is known?	Yes	No
✚ Have the details of the invention publicly disseminated?**	Yes	No

**For answering this question, one has to perform an online search, using the invention/creation keywords, in the following browsers/databases:*

[European Patent Office \(EPO\)](#)

[United States Patent and Trademark Office \(USPTO\)](#)

[PubMed Database](#)

[Spanish Patent & Trademark Office \(OEPM\)](#)

[Japan Patent Office \(JPO\)](#)

[SCOPUS Database](#)

An invention shall be taken to be new if it does not form part of the state of the art.

The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the country where the invention would be patented or elsewhere) by written or oral description, by use or in any other way.

***The discussion of the details related to the invention with fellow researchers, partners and advisors is considered as confidential. It is highly recommended to sign confidential agreements.*

- **Inventive Step (A). Values: 1-10.**

By contrast with **M** and **N**, inventive step (**A**) may be any value between 1 and 10. This test has an initial value of 1 and 3 points for each of the options/answers bold marked can be added up a total **A** value of 10.

✚ If the invention/creation is the combination of several ones, are their properties or functionality predictable if you know all its components? *	Yes	No
✚ If the invention/process is the solution to a problem, are there different solutions possible so the inventor had to research and select the best one? **	Yes	No
✚ Is the invention the replacement of one of the components of the product/process for a different one with equivalent properties?	Yes	No

**If the properties are greater than the sum of its parts, or better than expected, then it can be considered as a non-obvious invention. And then, the answer to the previous question should be "No".*

Summing up: patentability requires that several features are met (including: surprising technical advantages, unexpected technical effects). Mere aggregations (developments in one way street -lack of alternatives) are not patentable.

***If there is only one solution to a problem in a process, object or invention, and it could be deduced by a person skilled in the art, it might be considered obvious.*

- **Industrial Application (I). Values: 1-10**

This test has an initial value of 1, to which are added 3 points for each of the options/answers bold marked.

✚ Is the industrial field totally clear in the invention description? *	Yes	No
✚ Is the main application of the invention related to the private and personal sphere of human being?	Yes	No
✚ Is the invention described clear and complete enough for being carried out by a person skilled in the art? **	Yes	No
✚ Is the invention a method for treatment of the human or animal by surgery or therapy or a diagnostic method practiced on the human or animal body? ***	Yes	No

**It must be specified the industry the invention is addressed to (the term "Industry" is far-reaching). It is especially important when the invention refers to DNA sequences.*

An invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.

***Requirement of sufficiency of disclosure.*

Disclosure: the matter relied upon as prior art must disclose subject matter that, if performed, would necessarily result in an infringement of the patent.

******Eliminatory question.** If the answer to this question is "Yes" the P.I. automatically becomes "o". This restriction does not apply to an invention consisting of a substance or composition for use in any such method.*

Limits and mathematical interpretation (modelling of the formula)

As we mentioned above, our HP team has developed an equation for the field of intellectual property, based in the current laws on this issue.

$$P = M \cdot N \cdot \left(\frac{A+I}{2}\right)^{\log(A)} \quad (1)$$

Where:

$P \in \{0,1, \dots, 9,10\}$ is patentability.

$M \in \{0,1\}$ is morality.

$N \in \{0,1\}$ is novelty.

$A \in \{1,2, \dots, 9,10\}$ is inventive step.

$I \in \{1,2, \dots, 9,10\}$ is industrial application.

Both morality and novelty are strict criteria with only two possible values: they must be one in order to be patentable and they are the main barriers in patentability. Once they are overcome, patentability becomes more 'subjective'. This term is the most interesting, in a mathematical way, to analyse. So we can define:

$$P_c = \left(\frac{A+I}{2}\right)^{\log(A)} \quad (2.a)$$

or

$$P_c = A^{\log\left(\frac{A+I}{2}\right)} \quad (2.b)$$

Proof:

$$P_c = \left(\frac{A+I}{2}\right)^{\log(A)} \rightarrow \log(P_c) = \log\left(\left(\frac{A+I}{2}\right)^{\log(A)}\right) \rightarrow \log(P_c) = \log(A) \cdot \log\left(\frac{A+I}{2}\right) \rightarrow$$

$$\rightarrow \log(P_c) = \log\left(A^{\log\left(\frac{A+I}{2}\right)}\right) \rightarrow P_c = A^{\log\left(\frac{A+I}{2}\right)}$$

Using 2.b equation, A variable is more important than I. Independently of any value of I, patentability is always one when A takes the value of one.

The other extreme situation takes places when A is maximal: The patentability increases linearly with the Industrial application.

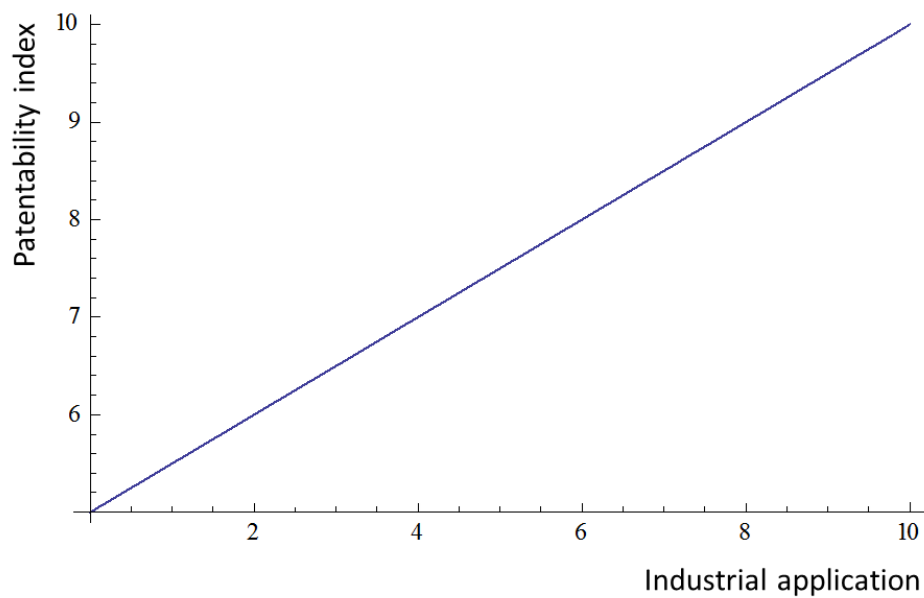


Figure 3. At a maximal value of **A**, the Patentability Index (**P.I.**) value increases in a linear way as industrial application as the Industrial application (**I**) does.

Here are three figures depicting the patentability as function of the **Industrial application** (**I**) and the **Inventive step** (**A**) -the terms of **Morality** (**M**) and **Novelty** (**N**) must be necessarily one if not, the final value of the **Patentability Index** (**P.I.**) would be zero and there it is not necessary consider **A** and **I** values.

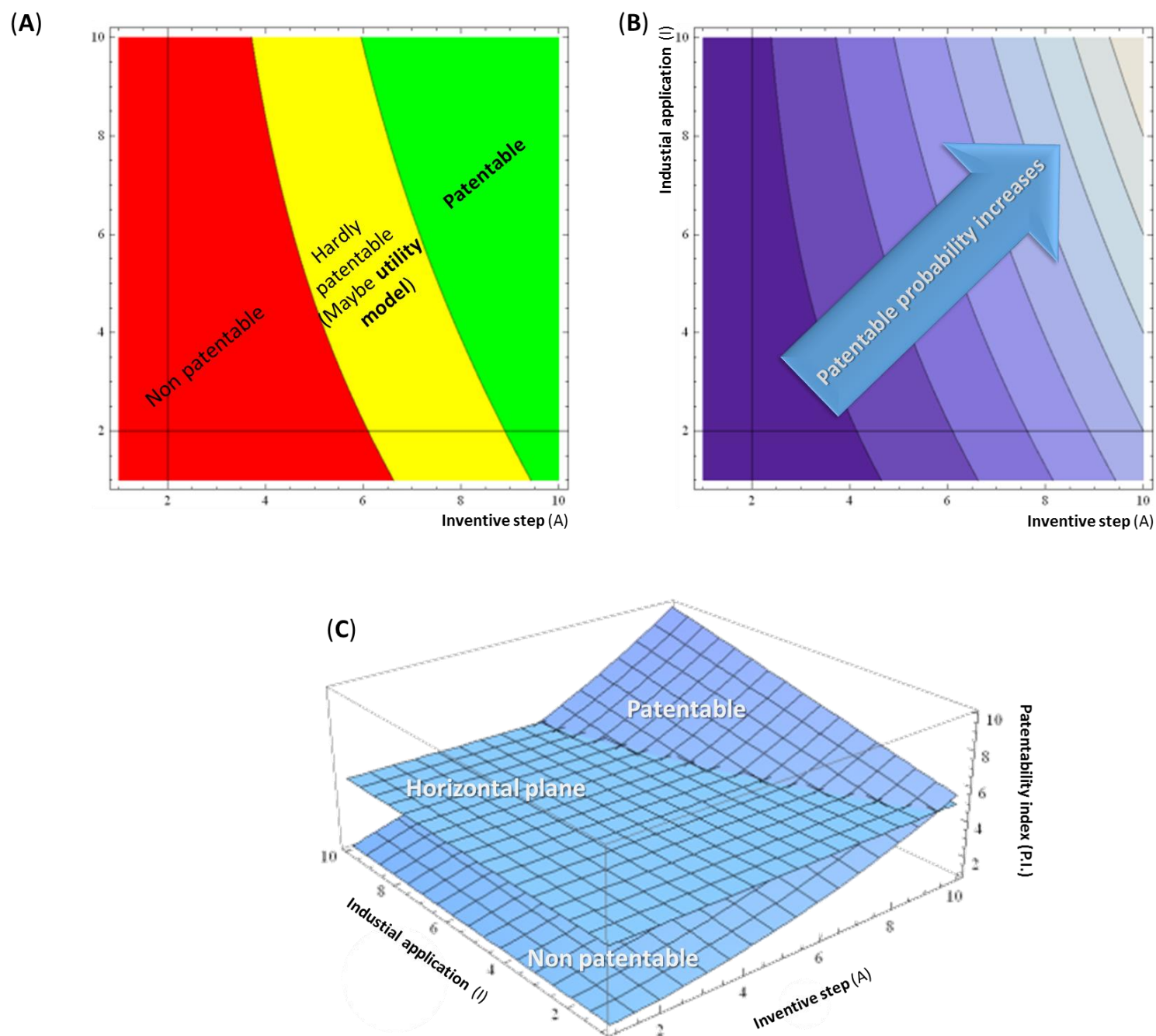


Figure 3. The picture A shows the main regions of patentability: no patentability in red, hardly patentable in yellow (in this case the inventor should consider protecting by utility model when it is allowed in the particular country or improve the invention in order to rise it to a stronger position in terms of patentability) and total patentability in green. In picture B the proportional regions depending of the different values taken by the A & I parameters (please note that the index final value rely stronger on A than on I). And finally, the third picture (C) shows the graphical representation of the formula in three dimensions with the separation at threshold of 5. In this last picture, the horizontal plane sets the limit of patentability.

B. DIRECTED EVOLUTION OF THE FORMULA (Experts' comments and suggestions)

In this subpart of the **Annex II** we are going to show the comments and suggestions from the experts we are sending the draft of the report to. It will be like an article process in which we are going to consider those comments as minor/major revisions to construct our definitive version of the formula.

Experts' comments and suggestions

“Should the formula (and its criteria / questions) be applicable internationally, i.e. beyond Europe? (e.g. regarding Morality (M) in the formula: US patent law does not (explicitly) require that inventions meet "moral standards", while the 'European Directive on Legal Protection of Biotechnological Inventions' does (and prohibits inventions that offend the "order public" / public morality).”

“Some sentences/explanations on what resources the user of the formula should refer to in order to answer human dignity questions (presumably you refer to case law or present/past judgments on similar/related patent claims; in any case, the approach might specified) could be included.”

“Decisions to file a patent claim are dependent on many interests/conditions and two different persons can take opposite decisions on the basis of the same information. This contextual interpretation might be stressed at some point (and it seems in line with your view that the formula does not replace "human decisions").”

“It would be appropriate to mention the TRIPS Agreement and the European Directive 98/44 on the legal protection of biotechnological inventions.”

“The legal rules make reference to “order public and morality”. The legal concepts are not exactly the same. If you want to summarize this concept with the expression “morality” it would be appropriate to specify and explain this.”

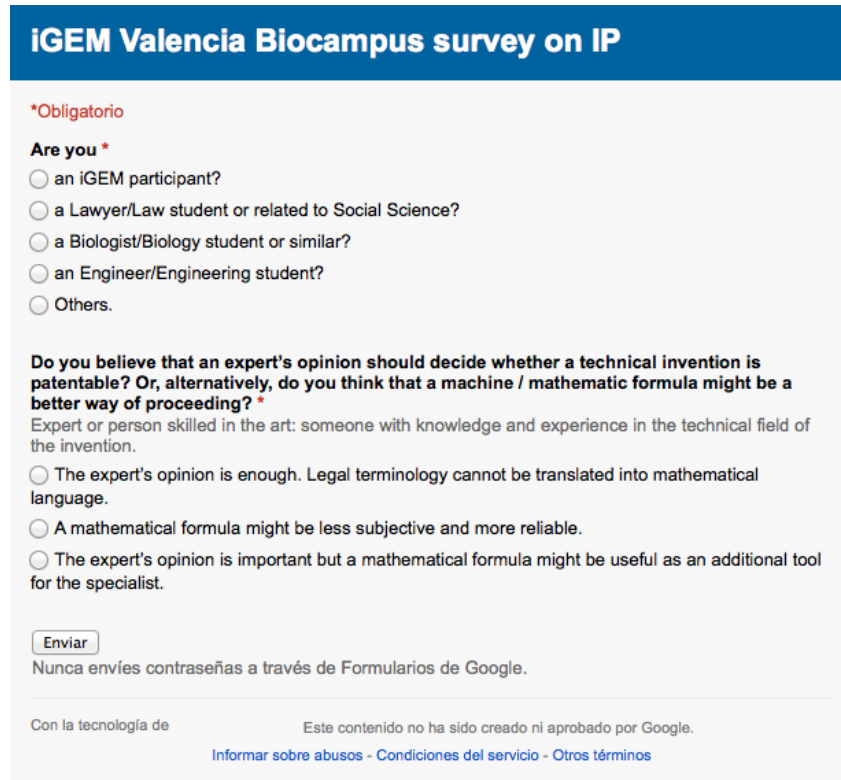
“The analysis of the cases *Diamond v. Chakrabarty*, *Association for Molecular Pathology et al. v. Myriad Genetics*, (US cases) and *Monsanto Technology LLC contra Cefetra BV e altri* (C-428/08) (UE Court of Justice) would be highly recommended.”
(Related to the morality test)

“In *Association for Molecular Pathology et al. v. Myriad Genetics* you will find that not necessarily a genetic sequence used for industrial reasons shall be patented [...], the difficulty in these kind of situation is not necessarily based on morality, but on the inventive step.”

C. iGEM VALENCIA BIOCAMPUS SURVEY ON IP

We conducted a survey in order to find out what is the opinion of society about our patentability formula and our idea of improving the IP framework. Thus, we carried out an online survey – in English and Spanish- focusing on specific groups. These groups are mainly iGEM participants, lawyers, biotechnologist and engineers.

The survey consisted of just a simple question about whether patentability of a technical invention should be decided by the person skilled in the art or it would be better to use a formula. We proposed three options to choose among them:



The image shows a screenshot of a Google Forms survey titled "iGEM Valencia Biocampus survey on IP". The form is in English and includes the following content:

- A blue header bar with the title "iGEM Valencia Biocampus survey on IP".
- A red asterisk indicating a mandatory question: "*Obligatorio".
- A question: "Are you *".
- Five radio button options for the question "Are you *":
 - ☐ an iGEM participant?
 - ☐ a Lawyer/Law student or related to Social Science?
 - ☐ a Biologist/Biology student or similar?
 - ☐ an Engineer/Engineering student?
 - ☐ Others.
- A second question: "Do you believe that an expert's opinion should decide whether a technical invention is patentable? Or, alternatively, do you think that a machine / mathematic formula might be a better way of proceeding? *".
- A subtext for the second question: "Expert or person skilled in the art: someone with knowledge and experience in the technical field of the invention."
- Three radio button options for the second question:
 - ☐ The expert's opinion is enough. Legal terminology cannot be translated into mathematical language.
 - ☐ A mathematical formula might be less subjective and more reliable.
 - ☐ The expert's opinion is important but a mathematical formula might be useful as an additional tool for the specialist.
- An "Enviar" (Send) button.
- A footer note: "Nunca envíes contraseñas a través de Formularios de Google."
- At the bottom, it says "Con la tecnología de" followed by the Google logo and "Este contenido no ha sido creado ni aprobado por Google."
- At the very bottom, there are links: "Informar sobre abusos - Condiciones del servicio - Otros términos".

Figure 4. English version of our online survey.

Results of the survey

After two months of the survey, we received some responses that could be represented by following pie charts (preliminary results on Sep 23 2014):

Number of participants (for the time being): 510 responses

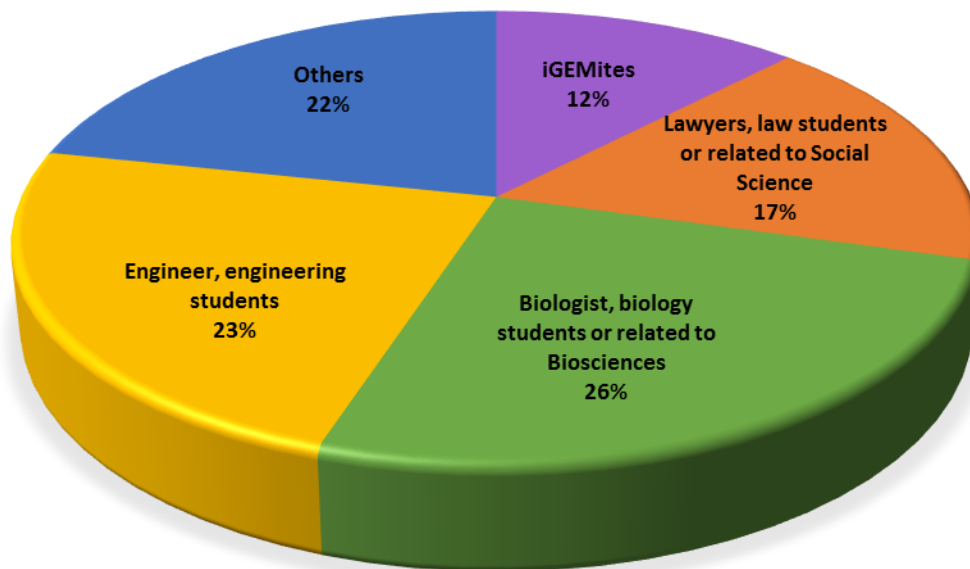


Figure 5. Percentage of participation –by background- in the survey (the final results will be displayed once the survey is closed, next 10th October).

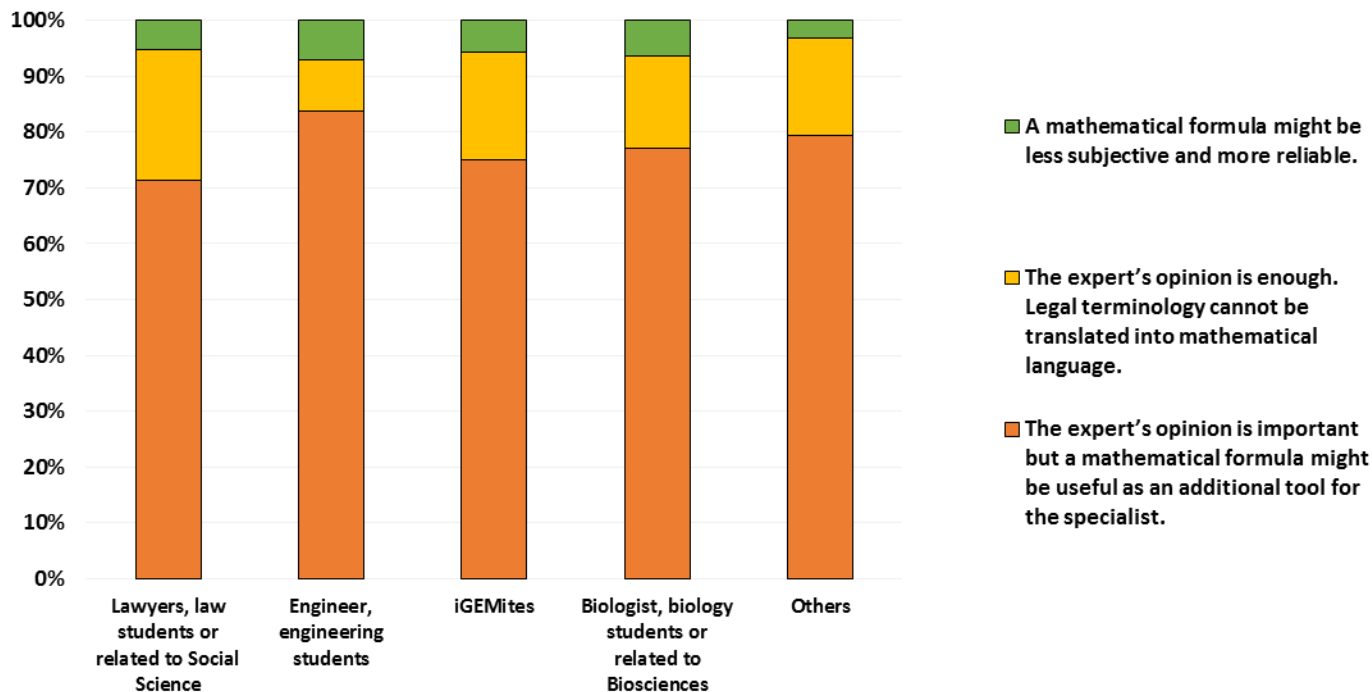


Figure 6. Preliminary results of our survey shown in percentage (the final results will be displayed once the survey is closed, next 10th October).

D. BIBLIOGRAPHY AND REFERENCES

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